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104TH CONGRESS
2D SESSION

H. R. 3691

To provide for the establishment of a Prescription Drug Price Review Board to identify excessive drug prices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 20, 1996

Mr. JOHNSON of South Dakota introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To provide for the establishment of a Prescription Drug Price Review Board to identify excessive drug prices, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Prescription Drug Consumer Protection Act of 1996''.

SEC. 2. ESTABLISHMENT OF BOARD.

(a) ESTABLISHMENT.—There is established in the executive branch the Prescription Drug Price Review Board (hereinafter in this Act referred to as the ''Board'').

(b) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Board shall be composed of 5 members appointed by the President, by and with the advice and consent of the Senate, from among individuals—

(A) who are recognized experts in the fields of consumer advocacy, medicine, pharmacology, pharmacy, and prescription drug reimbursement; and

(B) who have not worked in the pharmaceutical manufacturing industry during the 3-year period ending on the date of appointment.

(2) INITIAL APPOINTMENTS.—Initial appointments under paragraph (1) shall be made not later than 90 days after the date of the enactment of this Act.

(3) TERMS.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), each member shall be appointed for a term of 5 years.

(B) TERMS OF INITIAL APPOINTEES.—As designated by the President at the time of appointment, of the members first appointed—

(i) 1 member shall be appointed for a term of 1 year;

(ii) 1 member shall be appointed for a term of 2 years;

(iii) 1 member shall be appointed for a term of 3 years;

(iv) 1 member shall be appointed for a term of 4 years; and

(v) 1 member shall be appointed for a term of 5 years.

(C) VACANCIES.—A vacancy in the Board shall be filled in the manner in which the original appointment was made. Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of the member's term until a successor has taken office.

(4) INITIAL MEETING.—The initial meeting of the Board shall be held not later than 90 days after the date on which the first appointments of the members have been completed.

(5) CHAIRPERSON.—The President shall designate 1 member of the Board to serve as the chairperson.

(6) BASIC PAY.—

(A) IN GENERAL.—Members shall be paid at a rate not to exceed the daily equivalent of the maximum annual rate of basic pay payable under section 5376 of title 5, United States Code, for each day during which the members are engaged in the actual performance of the duties of the Board.

(B) TRAVEL EXPENSES.—Members shall receive travel expenses, including per diem in lieu of subsistence, in accordance with sections 5702 and 5703 of title 5, United States Code.

(c) DIRECTOR AND STAFF.—

(1) DIRECTOR.—The Board shall have a director who shall be appointed by the chairperson, subject to rules prescribed by the Board.

(2) STAFF.—The chairperson may appoint and fix the pay of such additional personnel as the chairperson considers appropriate, subject to rules prescribed by the Board.

(3) APPLICABILITY OF CERTAIN CIVIL SERVICE LAWS.—The director and staff of the Board shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the requirements of chapter 51 and subchapter III of

chapter 53 of such title relating to classification and General Schedule pay rates; except that an individual so appointed may not receive pay in excess of the maximum annual rate of basic pay payable for grade GS–15 of the General Schedule.

SEC. 3. POWERS OF BOARD.

(a) OBTAINING OFFICIAL DATA.—The chairperson of the Board may secure directly from any Federal agency information necessary to enable the Board to carry out its duties. Upon request of the chairperson, the head of the agency shall furnish such information to the Board to the extent such information is not prohibited from disclosure by law.

(b) MAILS.—The Board may use the United States mails in the same manner and under the same conditions as other Federal agencies.

(c) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the chairperson, the Administrator of General Services shall provide to the Board on a reimbursable basis the administrative support services necessary for the Board to carry out its duties.

(d) CONTRACT AUTHORITY.—The chairperson may contract with and compensate government and private agencies or persons for the purpose of conducting re-

search, surveys, and other services necessary to enable the Board to carry out its duties.

(e) INVESTIGATIONS.—The Board may make such investigations as it considers necessary to determine whether there is or may be a violation of any regulation promulgated under this Act and may require or permit any person to file with it a statement in writing, under oath or otherwise as the Board shall determine, as to all the facts and circumstances concerning the matter to be investigated.

(f) SUBPOENA POWER.—

(1) IN GENERAL.—The Board may issue subpoenas requiring the attendance and testimony of witnesses and the production of any evidence relating to any matter under investigation by the Board. The attendance of witnesses and the production of evidence may be required from any place within the United States at any designated place of hearing within the United States.

(2) FAILURE TO OBEY A SUBPOENA.—If a person refuses to obey a subpoena issued under paragraph (1), the Board may apply to a United States district court for an order requiring that person to appear before the Board to give testimony, produce evidence, or both, relating to the matter under inves-

tigation. The application may be made within the judicial district where the hearing is conducted or where that person is found, resides, or transacts business. Any failure to obey the order of the court may be punished by the court as civil contempt.

(3) SERVICE OF SUBPOENAS.—The subpoenas of the Board shall be served in the manner provided for subpoenas issued by a United States district court under the Federal Rules of Civil Procedure for the United States district courts.

(4) SERVICE OF PROCESS.—All process of any court to which application is made under paragraph (2) may be served in the judicial district in which the person required to be served resides or may be found.

SEC. 4. FUNCTIONS OF THE BOARD.

(a) GUIDELINES.—The Board shall—

(1) develop and publish within 9 months of the date of the establishment of the Board the initial guidelines that the Board will use in determining whether an existing price or an increase in the price of any prescription drug is excessive,

(2) develop and publish within 12 months of the date of the establishment of the Board the initial guidelines that the Board will use in determining

whether the initial price at which a prescription drug is first sold is excessive, and

(3) periodically review the guidelines developed under paragraphs (1) and (2) and make appropriate revisions.

(b) DETERMINATIONS AND REVIEWS.—The Board shall—

(1) within 24 months of the date of the establishment of the Board, make an initial determination of whether the price of each prescription drug approved for sale on the date of the enactment of this Act is excessive,

(2) promptly make an initial determination of whether the price of each prescription drug first approved for sale after the date of the enactment of this Act is excessive,

(3) review, on an ongoing basis, each increase in the price of a drug reviewed under paragraphs (1) and (2) to determine if the price increase is excessive, and

(4) consider whether determinations and reviews similar to the ones carried out under paragraphs (1), (2), and (3) should be made for non-prescription drugs and make such determinations and reviews if appropriate.

(c) FACTORS.—In making determinations under subsection (b) as to whether the price of a prescription drug is excessive, the Board shall take into consideration—

(1) changes in the producer price index (published by the Bureau of Labor Statistics of the Department of Labor),

(2) changes in the prescription drug component of such producer price index,

(3) the price at which such drug was sold to wholesalers in the United States during the preceding 10 years,

(4) the price at which such drug was sold to wholesalers in other countries during the preceding 10 years,

(5) the price at which other drugs in the same therapeutic class were sold to wholesalers in the United States during the preceding 10 years,

(6) the therapeutic potential rating of such drug by the Food and Drug Administration,

(7) the percentage of such drug's research and development costs paid by the United States,

(8) the cost of manufacturing and marketing such drug, and

(9) such other factors as the Board considers relevant.

(d) REPORTING.—The Board shall—

(1) promptly provide to consumers and health care providers the results of the Board's determinations under subsection (b) and the method used in each such determination,

(2) provide information to consumers and health care providers regarding prescription drug pricing and price increases by therapeutic class and manufacturer,

(3) provide to consumers and health care providers information regarding the Food and Drug Administration therapeutic potential rating of each prescription drug and the percentage of the research and development of each such drug paid by the United States,

(4) provide to consumers such other information as the Board determines will assist consumers in reducing their expenses for prescription drugs,

(5) publish an easy to understand consumer's guide to prescription drug prices, including the information described in paragraphs (1), (2), (3), and (4), within 24 months of the date of the establishment of the Board and update and publish such guide annually thereafter, and

(6) provide to the President and the Congress a report of its determinations under subsection (b) within 24 months of the date of the establishment of the Board and update and report such determinations annually thereafter.

SEC. 5. SANCTIONS AND REMEDIES.

(a) HEARINGS.—After making a determination under section 4(b) that the price of a prescription drug or an increase in the price of such a drug is excessive, the Board shall—

(1) notify, in writing, the manufacturer of such drug of such determination,

(2) fix a date on which a public hearing before the Board respecting such determination shall be held and hold such hearing,

(3) request from such manufacturer such additional information as the Board deems necessary for such public hearing, and

(4) notify such manufacturer of the Board's recommendation as to the pricing of the drug at a rate which is not excessive.

(b) SETTLEMENT.—If, after a public hearing under subsection (a), the Board finds that the price or an increase in the price of a prescription drug is not excessive, the Board shall—

(1) notify the manufacturer of such drug of the Board's finding, and

(2) remove from all publications and reports of the Board after the date of such finding any statement that the price or increase in the price of such drug is excessive.

(c) PATENT REVOCATION.—If, after a public hearing under subsection (a), the Board finds that the price or an increase in the price of a prescription drug is excessive, the Board shall—

(1) notify the manufacturer of such drug of the Board's finding,

(2) notify the manufacturer of such drug of the Board's intent to revoke the patent for such drug if the drug is patented or to revoke the patent of another drug of such manufacturer if such drug is not patented, and

(3) take such action as may be necessary to revoke a drug patent under paragraph (2) if the manufacturer of such drug does not reduce the price of the drug to a level that is not excessive.

SEC. 6. MANUFACTURERS.

Each manufacturer of a prescription drug subject to review under section 4 shall—

(1) provide to the Board such information as the Board may require to make the determinations under section 4, including—

(A) information identifying such drug,

(B) the price at which such drug is being sold or has been sold in any market,

(C) the cost of manufacturing and marketing such drug, and

(D) such other information as the Board considers necessary to be provided in such form and manner and at such time as the Board prescribes by regulation, and

(2) notify the Board immediately of any increase in the wholesale price of any prescription drug marketed by the manufacturer.

SEC. 7. STUDY.

The Board shall engage the Institute of Medicine of the National Academy of Sciences to conduct a study of prescription drug research and development and pricing practices, the difficulties many Americans have in affording prescription drugs, and options for making prescription drugs available to all that need them. Such study shall—

(1) examine Federal incentives for research and development and determine which incentives are

most effective and what changes would better encourage the development of low cost, effective drugs,

(2) examine the Federal regulatory process and identify ways it might be streamlined without jeopardizing consumer safety,

(3) consider whether the authority of the Food and Drug Administration should be enhanced and whether the funding for such agency should be increased to improve Federal regulation of drugs,

(4) consider steps the United States might take (including possible trade sanctions) to protect manufacturers of drugs in the United States from product pirating and other unfair trade practices by foreign competitors,

(5) consider changes in the patent laws (including delaying the start of a product's 17 years patent protection until after the product has been approved under the Federal Food, Drug, and Cosmetic Act) to allow manufacturers to charge lower prices and still recoup their research and development costs,

(6) consider whether a Board review of non-prescription drug prices would have a positive effect on consumer costs of such drugs,

(7) consider mechanisms to assist consumers with the high cost of prescription drugs (including

providing reimbursement under title XVIII of the Social Security Act for prescription drugs at lower prices negotiated with manufacturers of drugs),

(8) examine Federal policies regarding the licensing of drugs discovered and developed by federally funded researchers and recommend actions that would allow the United States to recoup its costs or to influence the pricing of such drugs, and

(9) examine the effects on retail pharmacies of disparities in drug prices wherein the drug manufacturers charge hospitals, mail order pharmacies, and health maintenance organizations significantly lower prices than those charged wholesalers for such drugs.

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